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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,963	12/16/1999	TOHRU TANAKA	Q57226	1604

7590

08/27/2002

SUGHRUE MION ZINN MACPEAK & SEAS  
2100 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20037

EXAMINER
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DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/27/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/445,963

Applicant(s)

TANAKA ET AL.

Examiner

Natalie A. Davis

Art Unit

1642

-- Th MAILING DATE of this communication appears on th cov r sh et with the correspond nc address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Information Disclosure Statement*

The information disclosure statement has been considered. A signed copy is attached hereto.

### *Transitional After Final Practice*

The finality of paper No. 6, mailed 28 August 2001 is withdrawn and prosecution is reopened.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy et al., (1994, ACS Symp. Ser., pp.291-302) in view of Jichlinski, et al., (1996, Pro. SPIE-Int. Soc. Opt. Eng. pp.340-347), Kajiwara (1990, JP 02111747), and Jaffe, et al., (1990, Biochemistry, pp.8345-50).

Kennedy et al. teach the treatment of tumors by administering 5-aminolevulinic acid (5-ALA) to patients with cancer, show the accumulation of fluorescing and/or photosensitizing concentrations of protoporphyrin IX in the malignant cells, and the subsequent treatment of malignant tissue by exposure to photoactivating light (abstract, p. 292, 295-6). Kennedy does not teach to use 5-aminolevulinic acid with at least one carbon and/or nitrogen isotope and the use of 5 ALA to detect tumors.

Jichlinski, et al. teach the usefulness of 5-ALA in the diagnosis and treatment of bladder cancer by show a good correlation of between the fluorescence findings, due to 5-ALA installation, and the histopathological diagnosis of bladder. Jichlinski further suggest the usefulness of 5-ALA in finding and treating residual malignant spots.

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Kajiwaru teach  $^{13}\text{C}$ -labeled 5-aminolevulinic acid and its derivatives for diagnostic purposes.

Jaffe, et al discloses using NMR to detect  $^{13}\text{C}$  and  $^{15}\text{N}$  isotopically replaced 5-aminolevulinic acid porphobilinogen complexes.

In view of the teachings of Kennedy, Jichlinski, Kajiwaru, and Jaffe, it would have been obvious to one having ordinary skill in the art at the time the invention was made to detect and treat malignant tumors using  $^{13}\text{C}$  and/ or  $^{15}\text{N}$  isotopically replaced 5-aminolevulinic acid. One would have been motivated to use the method as claimed since the combination of Kennedy and Jichlinski teach administration of 5-ALA as useful in the detection cancer and subsequent treatment of cancer using photoactivating light. Kajiwaru teach  $^{13}\text{C}$ -labeled 5-aminolevulinic acid for diagnostic purposes, and Jaffe teach detection of  $^{13}\text{C}$  and  $^{15}\text{N}$  isotopically replaced 5-aminolevulinic acid in porphobilinogen complexes. The use of either a fluorescence label or radiolabel in the detection scheme of Jichlinski is within the purview of one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD  
August 22, 2002

  
SHEELA HUFF  
PRIMARY EXAMINER